

REMARKS

The present claims are claims 1-7 and 9-23, with nonelected claims 20-22 being withdrawn from consideration. Claim 1 as amended defines that the biomaterial is a hydrogel, as supported by page 4, second full paragraph, for example. Claim 23 replaces claim 8. Favorable reconsideration of this application is respectfully requested.

Claims 1-18 were rejected under 35 USC 103(a) as unpatentable over Nicolson et al. (US 5,760,100) in view of Thiele (US 4,442,125). Reconsideration is requested.

The presently claimed invention is a method for treating a hydrogel biomaterial, that comprises contacting the surface of the hydrogel biomaterial with a cationic polysaccharide to inhibit the ability of the hydrogel biomaterial to sorb cationic antimicrobials.

As discussed in the present specification, cationic antimicrobials (for example, biguanides among others) are commonly used in hydrogel contact lens treating solutions, including solutions where the treated contact lens is inserted directly in the eye after treatment, i.e., without rinsing the lens with a separate solution. These antimicrobials offer good antimicrobial efficacy and relatively low eye irritation. However, certain cationic still have a tendency to irritate some persons' eyes when they are absorbed in the hydrogel contact lens. The presently claimed invention solves this problem by inhibiting ability of the hydrogel biomaterial to sorb the cationic antimicrobial, thus providing less eye irritation potential as well as increased comfort.

Nicolson et al. discloses an extended wear ophthalmic lens made of a hydrogel copolymer. Applicant respectfully disagrees with the assertion that "Nicolson et al. intrinsically discloses a similar composition for the prevention of preserving uptake into biomaterials as applicant is claiming."

The rejection references the ionoperm polymerizable materials of Nicolson et al. However, these are monomers that are copolymerized with the oxyperm polymerizable material to form a contact lens hydrogel copolymer. In other words, these monomers are not used to contact the surface of an already-polymerized hydrogel material, as defined in the present claims – rather, these monomers are copolymerized to form the bulk hydrogel copolymer material. Similarly, the various monomers disclosed at column 26, line 62 to column 27, line 25 are comonomers that form the bulk hydrogel copolymer.

The rejection references antimicrobial polymerizable materials such as poly(quaternary ammonium) salts which may be added to inhibit microbial growth on the lens material, with

specific reference to column 7, lines 42-54. First, this polymerizable antimicrobial is copolymerized with the ionoperm polymerizable material and the oxyperm polymerizable material to form the contact lens hydrogel copolymer. Thus, similar to the ionoperm polymerizable material discussed in the previous paragraph, these monomers are not used to contact the surface of an already-polymerized hydrogel material as defined in the present claims – rather, these monomers are copolymerized to form the bulk hydrogel copolymer material. Second, these antimicrobial polymerizable materials would inhibit microbial growth on the lens material because these materials have antimicrobial efficacy, *per se* – in other words, this polymerizable antimicrobial would impart antimicrobial properties to the bulk lens material so as to at least partially kill certain microorganisms contacting the lens. This really has nothing to do with inhibiting the ability of a biomaterial to sorb cationic antimicrobials.

The rejection references the use of the phosphate group in column 12, line 64 to column 13, line 8. However, this passage merely relates to a phosphate buffered saline solution for immersing the lens during the described Hydrodell Technique for determining water permeability of the lens. Applicant does not understand how this passage is relevant to the presently claimed method. Although this solution would contact a contact lens surface, the solution contains neither a cationic polysaccharide nor a cationic antimicrobial.

The rejection references poly(ethylene glycol) at column 19, line 41, but this is one of the reactants used in the synthesis of the Material A macromer segment disclosed at the top of columns 19-20. This macromer, in turn, is copolymerized with other comonomers to form the bulk hydrogel copolymer.

In summary, Nicolson et al. discloses a contact lens made of a hydrogel biomaterial. And the method of the present invention may be used with such a hydrogel biomaterial. Beyond that, Applicant does not understand how Nicolson et al. is considered relevant to the presently claimed invention.

Thiele et al. discloses a process for preventing microorganisms, such as mold, fungi, bacteria and/or virus, from attaching to a surface, as well as a process for detaching microbes from a surface. The process involves treating the microorganism and/or the surface with an antimicrobial solution. Please see the abstract and column 2, lines 40-44. The rejection cites various portions of Thiele et al, where theories of the mechanism are described. However, Thiele et al. teaches a different method than the presently claimed invention. Thiele et al. is concerned

with preventing microorganisms from attaching to a surface; the presently claimed invention is concerned with inhibiting the ability of a biomaterial to sorb cationic antimicrobials. Thiele et al. treats the surface with an antimicrobial solution; the presently claimed invention contacts the surface with a cationic polysaccharide.

In summary, even assuming it was proper to consider Nicolson et al. and Thiele et al. in combination (and Applicant does not agree), the references as combined fail to disclose or suggest various limitations of the present claims. This alone indicates that no *prima facie* case of obviousness has been established. Specifically, neither reference discloses sorption of cationic antimicrobials on a biomaterial surface, nor any need to address this problem; additionally, Applicant does not understand how either reference is considered to disclose treating a surface with a cationic polysaccharide for any reason, and especially not for inhibition of a biomaterial to sorb cationic antimicrobials.

Accordingly, withdrawal of the rejection is respectfully requested.

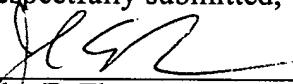
Claim 19 was rejected under 35 USC 103(a) as unpatentable over Nicolson et al. in view of Thiele, as applied to claims 1-18, and further in view of Billmers et al. (US 4,992,536). However, Billmers et al. does not cure the deficiencies of the other references, as discussed above. Although Billmers et al. discloses certain polycationic polysaccharides useful in the manufacture of paper, it still remains that no cited reference suggests inhibiting the ability of a biomaterial to sorb cationic antimicrobials. This alone indicates no *prima facie* case of obviousness has been established. Additionally, Applicant submits that a person of ordinary skill in the art of biomaterials, would not find the requisite motivation to incorporate the polycationic polysaccharides of Billmers et al. (disclosed for paper manufacturing) into the methods involving biomaterials disclosed in Nicolson et al. and/or Thiele et al.

The advisory regarding the Abstract of the Disclosure is noted. Applicant understands the current Abstract is in compliance. Although the current Abstract is less than 50 words, this advisory does not mandate that the Abstract must be at least 50 words.

ELECT AVAILABILITY

A favorable action in the form of a Notice of Allowance is requested. The Examiner is invited to contact the undersigned to resolve any remaining issues.

Respectfully submitted,


John E. Thomas
Registration No. 34,070
BAUSCH & LOMB INCORPORATED
One Bausch & Lomb Place
Rochester, NY 14604-2701
Telephone: (585) 338-8969

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claim 1 has been amended as follows:

1. (twice amended) A method for treating a hydrogel biomaterial comprising contacting the surface of said hydrogel biomaterial with a cationic polysaccharide to inhibit the ability of the hydrogel biomaterial to sorb cationic antimicrobials.

Claim 8 has been cancelled.

New claim 23 has been added:

-- 23. The method of claim 6 wherein the cationic charge on the cationic polysaccharide is derived from at least one selected from the group consisting of ammonium groups, quaternary ammonium groups, sulfonium groups, and phosphonium groups. --